



## EAST AFRICAN COMMUNITY

# PRESS RELEASE

### **APPROVAL OF THE EAC MEDICINES REGULATORY HARMONIZATION GUIDELINES BY THE 29<sup>TH</sup> MEETING OF THE COUNCIL OF MINISTERS (“the Council”) HELD AT EAC HEADQUARTERS, ARUSHA, TANZANIA ON 20<sup>TH</sup> SEPTEMBER 2014**

1. As part of implementation of the provision of EAC Treaty on Regional Cooperation on Health, Chapter 21, Article 118, the EAC Secretariat in collaboration with EAC Partner State’s National Medicines Regulatory Authorities (NMRAs) initiated the process of harmonizing technical requirements for the regulation of medicines to address lack of common approach in medicines regulation. The East African Community Medicines Regulatory Harmonization (EAC-MRH) scheme is collaboratively implemented by all the six (6) NMRAs in the EAC region namely; Department of Pharmacy, Medicines and Laboratories (DPML) of Burundi, National Drug Authority (NDA) of Uganda, Pharmacy and Poisons Board (PPB) of Kenya, Pharmacy Task Force (PTF) of Rwanda, Tanzania Food and Drugs Authority (TFDA) and Zanzibar Food and Drugs Board (ZFDB).
2. The Council of Ministers responsible for East African Community Affairs, during their 29<sup>th</sup> Ordinary Meeting held on 20<sup>th</sup> September 2014 in Arusha, Tanzania, approved for domestication and implementation of the EAC Medicines Regulation Harmonized guidelines with effect from January 2015 (**EAC/CM29/Decision 36**). These guidelines cover Medicines Evaluation and Registration (MER), Good Manufacturing Practices (GMP) and Quality Management System (QMS).
3. It is envisaged that the harmonized technical requirements and guidelines for regulatory approval of medicines will facilitate quick introduction of essential medicines on the market and reduced cost of doing business to pharmaceutical manufacturers.
4. **Annexes:**
  - I. Invitation for expression of interest – Submission of applications for Marketing Authorization of Medicinal Products in the EAC.
  - II. East African Community’s procedures for Marketing Authorization of Medicinal Products

5. For more information on EAC harmonized medicines registration and inspection guidelines, please contact the respective NMRAs at the following addresses:-

**a) National Drug Authority**

46-48 Lumumba Avenue  
P. O. Box 23096,  
Kampala,  
Republic of Uganda  
Tel: (+256) 414  
255665/347391/347392  
Email: ndaug@nda.or.ug

**b) Pharmacy and Poisons Board**

Lenana Road, Opp. the Russian Embassy  
P.O. Box 27663-00506  
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Republic of Kenya  
Tel: +254 20 3562107 – General Line  
Tel: +254 720 608811 – General Line  
Tel: +254 733 884411 – General Line  
E-mail: admin@pharmacyboardkenya.org  
E-mail: info@pharmacyboardkenya.org

**b) Department of Pharmacy,  
Medicines and Laboratories**

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Bujumbura,  
Republic of Burundi  
Tel: +257 22 27 97 40  
Tel: +257 22 27 97 39  
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Website: www.minisante.bi

**d) Pharmacy Task Force**


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Address:  
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Kigali,  
Republic of Rwanda  
Telephone: +250 577458  
Fax: +250 576853  
email: info@moh.gov.rw

**e) Zanzibar Food and Drugs Board**

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Phone: +255242233959  
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E-mail: drugs@zfdb.go.tz

**f) Tanzania Food and Drugs Authority**

Off Mandela Road, Mabibo-External  
P.O. Box 77150,  
Dar es Salaam,  
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Tel: +255 22 2450751/2450512/2452108  
GPS: -12.89748918375589, 36.5625  
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Email: info@tfda.or.tz  
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